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Attorneys for Plaintiffs
VERINATA HEALTH, INC.

and

THE BOARD OF TRUSTEES
OF THE LELAND
STANFORD JUNIOR
UNIVERSITY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

VERINATA HEALTH, INC.,

and

THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR
UNIVERSITY,

Plaintiffs,

v.

ARIOS A DIAGNOSTICS, INC.,

and

LABORATORY CORPORATION OF
AMERICA HOLDINGS,

Defendants.

Case No. 3:12-cv-05501-SI

**THIRD AMENDED COMPLAINT
FOR PATENT INFRINGEMENT**

JURY TRIAL DEMANDED

1 the State of California, including this District. For instance, Ariosa has acknowledged in *Ariosa*
2 *Diagnostics, Inc. v. Sequenom, Inc.*, Civil Action No. 11-03691 (N.D. Cal. Dec. 19, 2011) that it
3 “currently is, and has been, using the Aria Test in this District to conduct clinical studies in order
4 to validate the performance of the test in detection of fetal chromosome abnormalities.”
5 Likewise, LabCorp maintains numerous laboratory facilities in this district. On information and
6 belief, Defendants have purposefully directed a broad range of business activities at this District,
7 including among other things research, sales, blood collection and processing, and related
8 services. On information and belief, residents of this District have used services sold by or from
9 Defendants.

10 **JURISDICTION AND VENUE**

11 8. This action arises under the Patent Laws of the United States of America,
12 35 U.S.C. § 1 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28
13 U.S.C. § 1338(a) because this is a civil action arising under the Patent Act.

14 9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) because
15 a substantial part of the events giving rise to Verinata and Stanford’s claim occurred in this
16 District and because Defendants are subject to personal jurisdiction in this District.

17 **INTRA-DISTRICT ASSIGNMENT**

18 10. Pursuant to Civil Local Rules 3-5(b) and 3-2(c), because this action is an
19 intellectual property action, it is properly assigned to any of the divisions in this District.

20 **BACKGROUND**

21 11. Since its founding, Verinata’s activities have focused on developing and
22 offering non-invasive tests for early identification of fetal chromosomal abnormalities using its
23 proprietary technologies. In early 2012, Verinata began offering such a test, the verifi® prenatal
24 test, on a commercial basis. The verifi® prenatal test employs novel techniques to analyze cell-
25 free DNA circulating in the blood of a pregnant woman by DNA sequencing in order to
26 determine whether a fetus is at risk of having an abnormal number of chromosomes (sometimes
27 referred to as “aneuploidy”).
28

12. In or around May 2012, Ariosa and LabCorp began selling and offering to sell a commercial non-invasive prenatal test for Down syndrome, which they referred to by the trade name Harmony™ Prenatal Test. As Ariosa stated in a press release dated May 7, 2012, “[t]he Harmony Prenatal Test, which detects common fetal trisomies such as Trisomy 21 (associated with Down syndrome), will be offered through LabCorp and will be available at its 1,000+ patient service centers.”

13. The press release goes on to explain that the Harmony™ Prenatal Test “is performed using a simple maternal blood draw taken at a doctor’s office or patient service center.” Technical literature describing the technology underlying the Harmony™ Prenatal Test (which Ariosa identifies in a section of its website entitled “ABOUT THE SCIENCE”) explains that the method involves *inter alia* sequencing predefined subsequences of maternal and fetal DNA present in the maternal blood draw. *See, e.g.*, Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A., Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal Blood: Evaluation for Trisomy 21 and Trisomy 18, *Am. J. Obstet. Gynecol.* (2012). In view of this description, on information and belief Defendants’ Harmony™ Prenatal Test infringes the ’076 and ’430 patents directly and indirectly.

14. On information and belief, Defendants have and continue to sell and offer to sell the Harmony™ Prenatal Test. Likewise, on information and belief, defendants have and continue to use the Harmony™ Prenatal Test on samples of maternal blood. Likewise, on information and belief, LabCorp has and continues to encourage Ariosa to perform the Harmony™ Prenatal Test, intending that Ariosa perform the test.

15. On information and belief, LabCorp has and continues to supply to Ariosa material components of the Ariosa™ Prenatal Test having no substantial non-infringing use.

COUNT I (by Verinata and Stanford)

Infringement of U.S. Patent No. 8,296,076

16. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 15 above as relevant to this count.

1 17. On October 23, 2012, the United States Patent and Trademark Office duly
2 and legally issued the '076 patent, entitled "Noninvasive Diagnosis of Fetal Aneuploidy By
3 Sequencing."

4 18. Stephen Quake, Ph.D., and Hei-Mun Christina Fan, Ph.D., are the sole and
5 true inventors of the '076 patent. By operation of law and as a result of written assignment
6 agreements, Stanford obtained the entire right, title, and interest to and in the '076 patent.

7 19. Pursuant to license agreements Verinata entered into with Stanford,
8 Verinata obtained an exclusive license to the '076 patent in the field of genetic analysis by
9 nucleic acid sequencing.

10 20. On information and belief, Defendants have and continue to directly
11 infringe the '076 patent by practicing one or more claims of the '076 patent by, including without
12 limitation, selling, offering to sell, and using the Harmony™ Prenatal Test, and will continue to
13 do so, unless and until enjoined by this Court.

14 21. On information and belief, LabCorp has and continues to induce others to
15 infringe the '076 patent by, including without limitation, encouraging Ariosa to perform the
16 Harmony™ Prenatal Test, and will continue to do so, unless and until enjoined by this Court.

17 22. On information and belief, LabCorp has and continues to contributorily
18 infringe the '076 patent by, including without limitation, supplying to Ariosa material
19 components of the Harmony™ Prenatal Test having no substantial non-infringing use, and will
20 continue to do so, unless and until enjoined by this Court.

21 23. Defendants' infringement of the '076 patent has injured Plaintiffs in their
22 business and property rights. Plaintiffs are entitled to recovery monetary damages for such
23 injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

24 24. Defendants' infringement of the '076 patent has caused irreparable harm to
25 Plaintiffs and will continue to cause such harm unless and until their infringing activities are
26 enjoined by this Court.

COUNT II (by Verinata Only)**Infringement of U.S. Patent No. 8,318,430**

25. Plaintiff Verinata re-alleges and incorporates by this reference the allegations contained in paragraphs 1 through 24 above as relevant to this count.

26. On November 27, 2012, the United States Patent and Trademark Office duly and legally issued the '430 patent, entitled "Methods of Fetal Abnormality Detection."

27. Yue-Jen Chuu, Ph.D., and Richard P. Rava, Ph.D., are the sole and true inventors of the '430 patent. By operation of law and as a result of written assignment agreements, Verinata obtained the entire right, title, and interest to and in the '430 patent.

28. On information and belief, Defendants have and continue to directly infringe the '430 patent by practicing one or more claims of the '430 patent by, including without limitation, selling, offering to sell, and using the Harmony™ Prenatal Test, and will continue to do so, unless and until enjoined by this Court.

29. On information and belief, LabCorp has and continues to induce others to infringe the '430 patent by, including without limitation, encouraging Ariosa to perform the Harmony™ Prenatal Test, and will continue to do so, unless and until enjoined by this Court.

30. On information and belief, LabCorp has and continues to contributorily infringe the '430 patent by, including without limitation, supplying to Ariosa material components of the Harmony™ Prenatal Test having no substantial non-infringing use, and will continue to do so, unless and until enjoined by this Court.

31. Defendants' infringement of the '430 patent has injured Plaintiffs in their business and property rights. Plaintiff Verinata is entitled to recovery monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

32. Defendants' infringement of the '430 patent has caused irreparable harm to Plaintiff Verinata and will continue to cause such harm unless and until their infringing activities are enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Verinata and Stanford pray for relief as follows:

Verinata and Stanford

A. Judgment that Defendants have infringed, induced others to infringe, and/or contributorily infringed the '076 patent;

B. An order permanently enjoining Defendants from further infringement of the '076 patent;

C. An award of damages pursuant to 35 U.S.C. § 284;

D. An order for an accounting of damages from Defendants' infringement;

E. An award to Verinata and Stanford of their costs and reasonable expenses to the fullest extent permitted by law;

F. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and

G. An award of such other and further relief as the Court may deem just and proper.

Verinata Only

H. Judgment that Defendants have infringed, induced others to infringe, and/or contributorily infringed the '430 patent;

I. An order permanently enjoining Defendants from further infringement of the '430 patent;

J. An award of damages pursuant to 35 U.S.C. § 284;

K. An order for an accounting of damages from Defendants' infringement;

L. An award to Verinata of its costs and reasonable expenses to the fullest extent permitted by law;

M. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and

N. An award of such other and further relief as the Court may deem just and

proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b) and Civil Local Rule 3-6(a),
Verinata and Stanford hereby demand a trial by jury on all issues so triable.

Dated: March 8, 2013

Respectfully submitted,

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By: /s/ Edward R. Reines
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